949 7609502 09-Jun-2005 · 03:08 From-KNOBBE MARTENS OLSON BEAR T-968 P.012/019 F-652

Appl. No.

10/075,668

February 13, 2002 Filed

SUMMARY OF INTERVIEW

Exhibits and/or Demonstrations

See Examiner's Interview Summary. Applicant also demonstrated a commercially available CD HORIZON® MULTI-AXIAL SCREW, sold by Medtronic Sofamor Danek, Inc. and cross-sectioned sample of same, a collection of enlarged photographs of the cross-section screw, and assembled and unassembled samples of Applicant's commercial embodiments.

Identification of Claims Discussed

Identification of Prior Art Discussed

Farris et al. (US 6,485,491)

Proposed Amendments

See Examiner's Interview Summary

Principal Arguments and Other Matters

The proposed amendment to Claim 1 overcomes the rejection of record.

Results of Interview

See Examiner's Interview Summary

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REMARKS

Claims 1-5, 7-29, and 31-59 were pending in this application. In this Amendment, Applicant amends Claims 1, 14, 17-21, 23, 47, and 49. Claims 6, 24-46 and 50-59 are canceled. Accordingly, Claims 1-5, 7-23 and 47-49 remaining pending for a reconsideration.

Allowable Claims

In the Office Action, Claim 48 was indicated as being allowed. Claim 49 was indicated as being allowable if amended to overcome an objection to certain extraneous text identified by the Examiner. Claim 49 has been amended to cancel the extraneous text. Applicant respectfully requests allowance of Claim 49.

Terminal Disclaimer Filed Herewith To Overcome Double Patenting Rejection

Claims 1, 8-12, 14-16, 24, 32-36, and 38-41 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 8-15, 32-40, and 41 of co-pending Application No. 10/087,489. The '489 application has issued as U.S. Patent No. US 6,837,889.

However, Applicant respectfully submits that this rejection has been overcome by the amendments to the claims as presented herein. Nevertheless, if the claims are otherwise allowable, and the Examiner maintains this grounds of rejection, applicant will reconsider filing a terminal disclaimer.

The Pending Claims Are Patentable Over Farris

Claims 1-5, 7-12, 14-29, 31-47, and 50-59 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Farris, et al. (U.S. Patent No. 6,485,491).

The Farris reference was discussed thoroughly at the recent interview and also in the attached Declaration. Accordingly, detailed remarks here are not deemed necessary.

Farris

As discussed in the Declaration of Alan E. Shluzas Pursuant to 37 C.F.R. § 1.132, filed herewith (executed Declaration to follow), the embodiments described in this application specifically overcome problems with prior art bone anchors, such as the bone anchor described in U.S. Patent No. 6,485,491 to Farris et al. (the Farris patent).

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Farris Embodiment of Figure 53

The Farris patent discloses, in connection with Figure 53, reproduced below, a multi-axial bone anchor assembly 262 that includes a saddle member 22d, a bone anchoring member 24a, and a washer 26d.

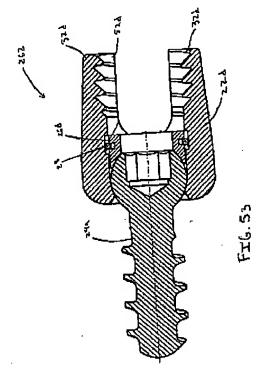
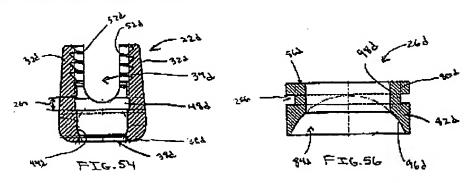


FIGURE 53

The saddle member 22d has a channel 34d (shown in Figure 54 reproduced below) that receives a rod 36. A snap ring 28 secures the washer 26d in the saddle member 22d. The snap ring 28 engages a snap ring recess 266 (shown in Figure 56 reproduced below).



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Even assuming that the saddle member 22d is a housing, the bone anchoring member 24a is a fastener, the washer 26d is a spacer, and the rod 36 is a longitudinal member, unlike the embodiments described in this application, the structure described in Figure 53 of the Farris patent would not prevent relative movement between a fastener and a housing and would not hold a longitudinal axis of the fastener in any one of a plurality of desired angular positions relative to a longitudinal axis of a passage in the housing when a longitudinal member is disengaged from a spacer.

Also, the Farris patent does not teaches an arrangement where a spacer necessarily engages a fastener when a longitudinal member is so disengaged. For example, in connection with Figure 53, the groove 48d (shown in Figure 54) is shown and described as having a thickness much greater than the thickness of the snap ring 28. This construction permits a separation between the washer 26d and the bone anchoring member 24a of at least about one-half the thickness of the groove 48d when the washer-and-snap ring assembly is slid to the top of the groove 48d and the bone anchoring member 24a is at the bottom position, abutting a surface at the bottom end of the channel 34d. Even if the structure of Figure 53 used a non-planar snap ring 28' as described at column 7, lines 32-43 of the Farris patent, such a structure would not produce the advantageous results of the embodiments disclosed in this application, as described above. This is particularly true because the Farris patent shows in Figure 53 that the groove 48d should be about four times the thickness of the snap ring, yet the non-planar snap ring 28' is only disclosed as being large enough to fill a greater, but not an entire, portion of the groove so as to allow less play between saddle member, anchoring member and washer.

As discussed in the *Declaration*, the foregoing shortcoming of the teachings of the Farris patent are manifest in the commercial embodiment currently being sold.

Other Embodiments

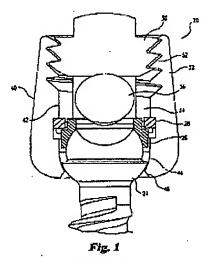
Other embodiments described in the Farris patent also do not disclose or suggest preventing relative movement between a fastener and a housing and holding a longitudinal axis of the fastener in any one of a plurality of desired angular positions relative to a longitudinal axis of a passage in the housing when a longitudinal member is disengaged from a spacer and the spacer engages the fastener. For example, the Farris patent in another embodiment relates to a

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posterior fixation system that includes a multi-axial bone anchor assembly 20, illustrated in Figure 1, reproduced below.



The bone anchor 20 is described in the Farris patent as having a saddle member 22, a bone anchoring member 24, and a washer 26. The saddle member 22 has a channel 34 that receives a rod 36. A snap ring 28 extends into a groove in the saddle member 22. The snap ring 28 would not necessarily prevent relative movement between the saddle member 22 and the bone anchoring member 24 and hold a longitudinal axis of the bone anchoring member in any one of a plurality of desired angular positions relative to a longitudinal axis of a passage in the saddle member when the rod 36 is disengaged from the washer 26. Nor does this embodiment of the Farris patent teach or suggest such a result.

A snap ring 28' is described in connection with Figure 17a (reproduced below) of the Farris patent that has a non-planar construction.

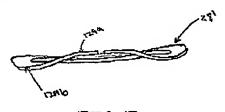


FIG. 17a

The snap ring 28' is said to reduce the play between the saddle member 22, the anchoring member 24, and the washer 26 because the non-planar snap ring fills a greater portion of the groove 48 in the saddle member. See column 7, lines 32-43 of the Farris patent. However, the

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snap ring 28' would not necessarily prevent relative movement between the saddle member 22 and the bone anchoring member 24 and hold a longitudinal axis of the bone anchoring member in any one of a plurality of desired angular positions relative to a longitudinal axis of a passage in the saddle member when the rod 36 is disengaged from the washer 26.

In particular, no axial force sufficient to prevent relative movement between a saddle member and a bone anchoring member is applied by the snap rings to the washers or anchoring members described in the Farris patent. Nor does this embodiment of the Farris patent teach or suggest such a result. Indeed, there is no arrangement shown or suggested in Farris in which "a member engaging both the horizontal indentation in the second passage and the radial surface of the spacer that applies an axial force to the spacer to prevent relative movement between said fastener and said housing.." as set forth in Claim 1, as amended. For example, if the anchoring member of the Farris arrangement were pushed up in at attempt to remove it vertically from the saddle member, the snap ring 28 or 28' would apply a downward force merely to secure (retain) the fastener within the housing (saddle member) (see Col. 7, L 12 – 14); however, in the absence of such a removal attempt, there is no teaching of a downward force sufficient to prevent relative movement between the housing and the screw, as recited below in Claim 1, as amended:

- 1. (Currently Amended) An apparatus for connecting a longitudinal member with a bone portion, comprising:
 - a longitudinal member connectable with a bone portion;
 - a fastener having a longitudinal axis and engageable with the bone portion to connect said longitudinal member to the bone portion;
 - a housing having a first passage configured to receive said longitudinal member, said housing having a second passage with a longitudinal axis extending transverse to said first passage, said fastener extending through an opening in said housing into said second passage and being movable relative to said housing, said longitudinal axis of said fastener being positionable in any one of a plurality of desired angular positions relative to said longitudinal axis of said second passage, the second passage having a horizontal indentation;

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a spacer received in said second passage of said housing and engageable with said fastener and said longitudinal member and having a radial surface below said indentation; and

a member engaging both the horizontal indentation in the second passage and the radial surface of the spacer that applies an axial force to the spacer to preventing relative movement between said fastener and said housing and holding said longitudinal axis of said fastener in any one of said plurality of desired angular positions relative to said longitudinal axis of said second passage when said longitudinal member is disengaged from said spacer and said spacer engages said fastener, said fastener and said housing being manually movable relative to each other against said force when said longitudinal member is disengaged from said spacer and said member applies said force;

a clamping mechanism that clamps said longitudinal member, said spacer and said housing to said fastener to prevent movement of said fastener relative to said housing.

CONCLUSION

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

For the foregoing reasons, the Applicant respectfully submits that the present application is in condition for allowance, and the Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity.

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Respectfully submitted,

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